



## The University of Arizona Consent to Participate in Research

**Study Title:** Effects of two psychosocial wellness workshops on sleep, stress management and well-being: Exploration of psychophysiological mechanisms

**Principal Investigator:** John J.B. Allen, Ph.D.

**Sponsor:** Mind & Life Institute (Francisco J. Varela Award)

**This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

### ***Why is this study being done?***

The transition through early adulthood, particularly for college students, is accompanied by several major life changes and challenges. For many individuals, this is a period that involves a move away from home, new social groups, and greater financial and academic responsibilities. The emotional stress associated with these changes is often associated with less time devoted to sleep, increased alcohol intake, reduced academic performance, and increased rates of anxiety and/or depression. This study explores the impact of health-promoting techniques taught in a workshop format on students' stress physiology and well-being.

### ***What will happen if I take part in this study?***

Following the online pre-screening and informed consent, you will complete another set of questionnaires, as well as one week of wearing a device on your wrist that measures activity, and also completing sleep diaries during that week. After this, the first laboratory visit will involve height and weight measurement, then recordings of electrocardiography (3 electrodes placed on your collarbone and lower left side near your ribs), respiratory inductance plethysmography belts (two bands across your abdomen), and pulse oximetry (a padded clip around your pointer finger), along with four saliva samples used to measure cortisol, and a few other simple questionnaires in conjunction with a stress induction task. The stress induction task lasts 10 minutes and involves alternating cycles of inserting your hand in an ice bucket and solving math problems out loud. The laboratory sessions will be video recorded.

After completing the first laboratory visit, you will participate in the assigned workshop held across four consecutive days at standard times (Thursday and Friday, 6:00-9:30pm, Saturday 10:00am-3:30pm, and Sunday 10:00am-3:30pm). The workshop will take place on campus with other student participants and will involve discussions and other activities in a group format aimed at understanding the nature of stress and providing techniques to enhance stress management and daily well-being. During the workshop, you will be asked to complete two additional, simple surveys.



Following the workshop, you will complete two additional laboratory visits (one within 1-2 weeks following workshop completion and then again approximately one month later) with associated online questionnaires, wrist actigraphy, sleep diaries, and experimental procedures similar to the first laboratory visit. You will receive your first payment of \$60 upon completion of the second laboratory visit and a second payment of \$40 upon completion of the third visit.

***How long will I be in the study?***

Once enrolled, your participation in the study is expected to last 2-3 months. The first laboratory visit will occur within 1-2 weeks prior to the next available workshop and the final laboratory visit will occur 4-8 weeks following workshop completion. The data you provide during the course of the study will be de-identified upon termination of primary data analysis and kept indefinitely for potential use in future research. Our efforts to maintain confidentiality are described in detail below.

***How many people will take part in this study?***

A total of 100 participants are expected to enroll in this study. All participants must meet the following criteria:

- a) 18-35 years of age
- b) Current identification with student status, which may include undergraduate, graduate, continuing studies, or post-baccalaureate/pre-doctoral
- c) No history of panic disorder or mania (with or without psychotic features), which may be risk factors for adverse effects of the yogic breathing intervention

***Can I stop being in the study?***

**Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

***What risks, side effects or discomforts can I expect from being in the study?***

This study is considered to involve minimal risk to you as a participant. Your participation in the workshop involves interaction with other participants and possible discussion of personal background information that may be uncomfortable for you. Some participants with sensitive skin may experience mild discomfort at the electrode sites for ECG data collection and around the wrist from wearing the Actiwatch. However, the equipment used for ECG recordings is widely used for research and clinical purposes with minimal adverse reactions reported, and the Actiwatch device has been tested for safety and has been FDA approved for use in adults.

Please report any skin irritations related to study procedures to research personnel and seek medical care if the irritations persist longer than 24 hours.



***What benefits can I expect from being in the study?***

You may or may not benefit as a result of participating in this study. It is possible that you may gain new stress-management tools to enhance overall well-being, although some may benefit more than others in one workshop or the other. You may also benefit by contributing to scientific knowledge about stress physiology and well-being of college students and other adults.

***What other choices do I have if I do not take part in the study?***

You may choose not to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

***Will my study-related information be kept confidential?***

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The University of Arizona Institutional Review Board or Office of Responsible Research Practices

***What are my rights if I take part in this study?***

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study. You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study. You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. An Institutional Review Board responsible for human subjects' research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

***What are the costs of taking part in this study?***

The primary cost to you will be time—time spent travelling to the laboratory, and time spent participating in the experiment. The initial sets of online questionnaires are estimated to take 30 minutes to complete, each laboratory visit approximately 90 minutes, and the workshop a total of 15 hours across the four consecutive days. There are no other significant costs associated with participation in this experiment.

***Will I be paid for taking part in this study?***

You will receive up to \$100 for participation in this study. Payment will be provided at two points: \$60 upon completion of the post-workshop laboratory visit and an additional \$40 upon



completion of the final laboratory visit one to two months following the workshop. To help ensure appropriate attendance at the workshops, which is critical to enable group cohesiveness as part of the workshop benefit for individual participants, payment will not be pro-rated for discontinuation prior to completion of the post-workshop laboratory visit.

**What happens if I am injured because I took part in this study?**

Injury in this experiment is very unlikely. However, if you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

**When may participation in the study be stopped?**

You may be requested to stop participation in this research study by the investigator if study procedures are not followed, such as incomplete workshop attendance.

**Who can answer my questions about the study?**

For questions, concerns, or complaints about the study you may contact John JB Allen at John.JB.Allen@arizona.edu. For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at <http://orcr.arizona.edu/hssp>. If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **John.JB.Allen@arizona.edu**.

**Optional future research participation**

\_\_\_\_\_ I give permission to be contacted by the Study Coordinator or Principal  
Subject initials Investigator of this study to contact me in the future regarding  
participation in related follow-up research studies.

**Signing the consent form**

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

\_\_\_\_\_  
Printed name of subject

\_\_\_\_\_  
Signature of subject

\_\_\_\_\_  
Date and time

AM/PM

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Consent Form T502a v 2015-03